UNITED STATES PATENT AND TRADEMARK OFFICE

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East Brunswick, NJ 08816

In re: Patent Term Extension
Application for
U.S. Patent No. 6,127,425

NOTICE OF FINAL DETERMINATION -- INELIGIBLE

An application for extension of the patent term of U.S. Patent No. 6,127,425 under 35 U.S.C. § 156 was filed in the United States Patent and Trademark Office on December 12, 2005. The application was filed by Savient Pharmaceuticals, Inc., the patent owner of record. Extension is sought based upon the premarket review under § 505 of the Federal Food, Drug, and Cosmetic Act (FFDCA) of a human drug product known by the tradename SOLTAMOX® and having the active ingredient tamoxifen citrate. SOLTAMOX® was approved for commercial use and sale by the Food and Drug Administration (FDA) on October 29, 2005.

A determination has been made that U.S. Patent No. 6,127,425 is **NOT** eligible for patent term extension under 35 U.S.C. § 156 based upon the regulatory review period of SOLTAMOX® (tamoxifen citrate for oral administration).

A single request for reconsideration of this FINAL DETERMINATION OF INELIGIBILITY may be made if filed by the applicant within TWO MONTHS of the mailing date of this letter. The period for response may be extended pursuant to 37 C.F.R. 1.136. See 37 C.F.R. 1.750. A failure to respond to this letter will result in the application papers being placed into the patent file with no further action taken on the application for patent term extension.

The FDA official records indicate that NOLVADEX®, having the active ingredient tamoxifen citrate, was previously approved for commercial marketing or use. See http://www.accessdata.fda.gov/scripts/cder/ob/docs/obdetail.cfm?Appl_No=017970&TABLE1=OB_Rx (last accessed April 2, 2007). The approval of NOLVADEX® was prior to the approval of SOLTAMOX®. In a letter dated July 24, 2006, FDA stated:

> A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). However, our records also indicate that the product, tamoxifen citrate, does not represent the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1), and interpreted by the courts in Glaxo Operations UK Ltd. v. Quigg, 706 F. Supp. 1224 (E.D. Va. 1989), aff'd. 894 F. 2d 392 (Fed. Cir. 1990).

Under 35 U.S.C. § 156(a) a term of a patent which claims a product shall be extended if, *inter*

alia, the product has been subject to a regulatory review period before its commercial marketing or use. In addition, under § 156(a)(5)(A):

> the permission for the commercial marketing or use of the product . . . is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred; (Emphasis added)

Thus, the determination of eligibility of U.S. Patent No. 6,127,425 turns on the provisions in § 156(a)(5)(A) that the permission for the commercial marketing or use is the first permitted commercial marketing or use of the product. The term "product" is defined in 35 U.S.C. § 156(f) as follows:

> (f) For purposes of this section:
> (1) The term "product" means:
> (A) A drug product . . .
> (2) The term "drug product" means the active ingredient of -
> (A) A new drug, antibiotic drug, or human biological product . . . .including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient. (Emphasis added.)

By the explicit terms of section 156(f)(2), the term "product" as it relates to a human drug product means the active ingredient of the new drug product. The active ingredient in the approved product SOLTAMOX® is tamoxifen citrate. As noted in the above FDA letter, the active ingredient tamoxifen citrate had been approved for commercial marketing and use prior to the approval of the applicant's product. Furthermore, the prior approval of the active ingredient tamoxifen citrate in NOLVADEX® by the Food and Drug Administration was under section 505 of the FFDCA, the same provision of law under which regulatory review of the product SOLTAMOX® occurred. Applying the definition of "product" provided in section 156(f) to the extension requirement of § 156(a)(5)(A), applicant's product, SOLTAMOX®, does not qualify as the first permitted marketing or use of the active ingredient. Since the approval of SOLTAMOX® was not the first permitted marketing or use of the active ingredient thereof, tamoxifen citrate, the patent is not eligible for patent term extension based upon the regulatory review of SOLTAMOX®. See In re Fisons Pharmaceuticals Limited, 231 USPQ 305 (Comm'r Pats. 1986); aff'd, Fisons plc v. Quigg, 8 USPQ2d 1491 (DDC 1988); aff'd, 10 USPQ2d 1869 (Fed. Cir. 1988); Glaxo Operations UK Ltd. v. Quigg, 13 USPQ 1628 (Fed. Cir. 1990).

It is noted that according to the application for patent term extension, the first approval of tamoxifen citrate was under to 21 U.S.C. § 355(b)(1), while permission to market SOLTAMOX® was granted under 21 U.S.C. § 355(b)(2). There is no suggestion in the legislative history that the phrase "first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred" as used in 35 U.S.C. § 156(a)(5)(A) is intended to treat different subparagraphs of 21 U.S.C. § 355(b) as different provisions of law. The Supreme Court in Eli Lilly and Co. v. Medtronic, Inc., 496 U.S.

661, 667, 674, 15 USPQ2d 1121, 1125-26, 1128 (1990), while making a distinction between the term "law" as broadly construed and a "provision of law," identified § 355 as a "provision" of the Federal Food, Drug, and Cosmetic Act under which new drugs are subject to premarket approval.

In view of the above, the term of U.S. Patent No. 6,127,425 is not eligible for extension under 35 U.S.C. § 156 based upon the approval of the product SOLTAMOX® (tamoxifen citrate for oral administration) and the application for patent term extension, filed December 12, 2005, is dismissed.

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX: (571) 273-7754

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7754.

Kathleen Kahler Fonda
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Office of Regulatory Policy
HFD - 7
5600 Fishers Lane
Rockwall II Rm. 1101
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Attention: Beverly Friedman

Re: SOLTAMOX® (tamoxifen citrate for oral administration)

FDA Docket No. 2006E-0250